Doc Code: AP.PRE.REQ

PTO/SB/33 (12-08)
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PRE-APPEAL BRIEF REQUEST FOR REVIEW	Docket Number (Optional) 98-P0151US2

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(Signature)

Application Number	Filed
10/789,398	February 27, 2004

First Named Inventor: Kathleen M. Miller

Art Unit	Examiner
3774	Thomas Sweet

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).
Note: No more than five (5) pages may be provided.

I am the

- [ ] applicant /inventor.
- [ ] assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)
- [x] attorney or agent of record. Registration number 29,674
- [ ] attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34. _____

/Rosemary M. Miano/
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August 21, 2009
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NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.

[x] *Total of 1 forms are submitted.

REASONS FOR REQUESTING PRE-APPEAL REVIEW

1) Status of Claims

Claims 1-104 are pending in the application. Claims 1-72 have been withdrawn pursuant to an election requirement. Claims 73-104 have been rejected and are presented for this Pre-Appeal Review.

2) The Rejection Under 35 U.S.C. § 102(a)/(e) – MODAK is Erroneous

Claims 73-75, 80, 89, 95-97 and 103 have been rejected under 35 U.S.C. § 102(a) or (e) as being anticipated by Modak et al. (U.S. Pat. No. 6,224,579) ("MODAK"). This rejection is believed to be in error.

For this rejection the focus is on independent Claims 73 which provides for:

A stent comprising a polymeric tubular shaft having more than one layer, said polymeric tubular shaft comprising a first annular layer comprising a matrix polymer, an antimicrobial agent and a microbial attachment/biofilm synthesis inhibitor, a first polymeric barrier layer at least partially covering an interior surface of said first annular layer and a second polymer barrier layer at least partially covering an exterior surface of said first annular layer.

In order for MODAK to be an effective reference under §102 and anticipate the rejected claims, MODAK must disclose each and every element of the claim. *See* MPEP 2131 and cases cited therein, *especially Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989) and *In re Marshall*, 578 F.2d 301, 304, 198 USPQ 344, 346 (Fed. Cir. 1978) (emphasis added). MODAK does not meet this standard.

MODAK does not teach each and every element of the claimed invention. More specifically, MODAK fails to teach all of the elements of the present invention as claimed in amended independent Claim 73, which is directed to:

> A stent comprising a polymeric tubular shaft having more than one layer, said polymeric tubular shaft comprising a first annular layer comprising a matrix polymer, an antimicrobial agent and a microbial attachment/biofilm synthesis inhibitor, *a first polymeric barrier layer at least partially covering an interior surface of said first annular layer and a second polymer barrier layer at least partially covering an exterior surface of said first annular layer*. (emphasis added).

More particularly, MODAK does not teach either a first or a second barrier layer that at least partially covers an exterior and interior surface, respectively of a first annular layer. Indeed, the words "barrier" or "barrier layer" do not appear anywhere in MODAK.

In the most recent Office Action preceding the Advisory Action, the Examiner failed to cite any portion of MODAK which describes such barrier layers. Instead, the Examiner mistakenly refers to layers in MODAK which contain active ingredients and that are applied by a dip coating process as barrier layers when, in fact, these layers contain active ingredients rather than being barrier layers. The Examiner has maintained this logic in the Advisory Action stating:

To be abundantly clear, the rejection is based on section 4.6 of Modak et al (62224579) the first annular member is the base polymer impregnated with the drugs (a drug matrix polymer) and then further coated with another drug polymer which controls the release rate (like it or not in the broadest reasonable interpretation of the claims, this layer is a barrier layer for the base polymer inherently controling [sic] its release rate).

Such an interpretation is a mischaracterization of MODAK. In fact, the full Section 4.6 of MODAK describes the concept as controlled release and does not teach or suggest the concept of a barrier layer. The full Section 4.6 of MODAK reads as follows:

4.6 TWO-STEP METHOD OF PREPARING ANTI-INFECTIVE MEDICAL ARTICLES
According to the two-step method of the invention, the one-step method may be used to impregnate a medical article with trielosan [sic] *and/or other chlorinated phenol and a silver compound, and then the medical article may be dipped into a second treatment solution containing triclosan and/or other chlorinated phenol and/or a silver compound and/or one or more polymer, and dried. This method forms a coating on the article and further controls the rate of release of triclosan or other chlorinated phenol and silver compound. For a non-limiting specific example, see Section 7, below.*

Specifically, MODAK uses a treatment solution with chlorinated phenols in combination with one or more silver compounds (col. 2, lines 47-52) and provides:

Medical articles prepared according to the invention may be treated on their external surface, internal surface, or both. For example, and not by way of limitation, where the medical article is a catheter, the internal surface and/or external surface of the catheter may be treated according to the invention. For example, where it is desired to treat both internal and external surfaces, an open-ended catheter may be placed in a treatment solution such that the treatment solution fills the catheter lumen. If only the external surface is to come in contact with treatment solution, the ends of the catheter may be sealed before it is placed in the treatment solution. If only the

internal surface is to come in contact with treatment solution, the solution may be allowed to pass through and fill the lumen but the catheter is not immersed in the treatment solution. (MODAK, col. 5, lines 32-47, emphasis added)

Although the other independent claim, Claim 87, is not listed in the current rejection (but discussed here as a foundation for the discussion of a following rejection below), it should be noted that MODAK also fails to teach all of the elements of the present invention as claimed in Claim 87, which is directed to:

> A ureteral stent comprising a polymeric tubular shaft that is between 0.2 mm and 0.8 mm in wall thickness, said polymeric tubular shaft having more than one layer and comprising a first annular layer comprising (a) polymeric species consisting essentially of ethylene vinyl acetate copolymer and (b) antimicrobial species consisting essentially of triclosan;
> *a first polymeric barrier layer at least partially covering an interior surface of said first annular layer;*
> *and a second polymer barrier layer at least partially covering an exterior surface of said first annular layer.* (emphasis added).

Again, as noted above for Claim 73, the Examiner mistakenly refers to layers that are applied by a dip coating process as barrier layers when, in fact, these layers of MODAK contain active ingredients rather than being barrier layers.

In addition to failing to teach all of the claimed elements, MODAK fails to teach the overall stent structure as it is presently claimed. The current invention is directed to an annular layer in the middle, with outer barrier layers such that at least a part of the interior surface of the annular layer is covered with a first barrier layer and at least a part of the exterior surface of the annular layer is covered with a second barrier layer. MODAK simply does not teach this type of multi-layered structure.

The Examiner's rejection of Claims 75, 80, 89, and 97-99 is similarly traversed for the reasons described above.

Thus, the rejections under MODAK under §102 should be withdrawn.

Rejection Under 35 U.S.C. §102(e)/103(a) Based on MODAK

Claims 84 (melt extruded tubular shaft depending from Claim 73) and 90 (melt extruded tubular shaft depending from Claim 87) are rejected under 35 U.S.C. §102(a)/(e) as being

anticipated by, or in the alternative, under 35 U.S.C. §103(a) as obvious over MODAK. The rejections under §102(a)/(e) are traversed for the reasons explained above for Claims 73 and 87. The rejection under §103(a) is traversed since MODAK by itself does not teach or suggest each of the elements of the claimed invention and the Examiner has not combined MODAK with any other reference for this rejection to cure the deficiencies of MODAK.

Rejections Under 35 U.S.C. §103(a) Based on MODAK, SCHWARZ, BUSCEMI and FALK

Claims 81-88 and 94 are rejected under 35 U.S.C. §103(a) as being obvious over MODAK. The rejection under §103(a) is traversed since MODAK by itself does not teach or suggest each of the elements of the claimed invention as noted above for Claims 73, 87, 84 and 90 and the Examiner has not combined MODAK with any other reference for this rejection. The additional limitations described in Claims 81, 82, 83 and 88 do not overcome the deficiencies in MODAK.

The discussion of Claim 87 is found above under the discussion of §102. Since MODAK is deficient for independent Claims 73 and 87, it is also deficient for all the claims depending therefrom. Also, since MODAK is not being combined with any other reference for this rejection, the deficiencies have not been cured.

Claims 76-79 and 91-93 are rejected under 35 U.S.C. §103(a) as being unpatentable over MODAK in view of Schwarz et al. (U.S. Publication No. 2001/0022988) ("SCHWARZ"). This rejection is traversed for the reasons described above for Claims 73 and 87. SCHWARZ is cited to provide a teaching of ethylene vinyl acetate copolymer, but SCHWARZ is directed to completely different coating methods including, e.g., ionization deposition, plasma treatment and grafting as noted in paragraphs 51-52 of SCHWARZ. Such coating methods are not combinable with the dip techniques described in MODAK and SCHWARZ is not combinable with MODAK.

Claims 100-101 are rejected under 35 U.S.C. §103(a) as being unpatentable over MODAK in view of Buscemi et al (U.S. Patent No. 5,693,034) ("BUSCEMI"). This rejection is traversed for the reasons described above for Claims 73 and 87. In addition, BUSCEMI is directed to hydrogels which is subject matter that has no relevance to the present invention.

Claims 102 and 104 are rejected under 35 U.S.C. §103(a) as being unpatentable over MODAK in view of SCHWARZ and further in view of Falk et al. (U.S. Patent No. 6,048,844) ("FALK") , with the citation of FALK being limited to the use of ketorolac as an anti-inflammatory agent. This rejection is traversed for the reasons described above for Claims 73 and 87 and of Claims 76-79 and 91-93 with respect to MODAK in view of SCHWARZ. The citation of FALK does not overcome the deficiencies of MODAK and SCHWARZ.

Thus, it is believed that the Examiner has not met his burden of establishing a *prima facie* case of obviousness which requires 1) some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings; 2) a reasonable expectation of success; and 3) a teaching or suggestion of all the claimed features. In addition, the teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure. (See *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991)).

Thus, the rejections under §103(a) are believed to be in error and should be reversed.

Comment on "Coating" Term

The Examiner's previous withdrawal of a rejection under 35 U.S.C. §112 regarding Claims 96, 98 and 99 in the Office Action preceding the current Advisory Action contains comments on the term "coating" as related to MODAK not being layered. This comment is not understood to be a rejection and its relevance has not been connected to any of the pending rejections.

For at least these reasons, Applicant respectfully submits that the Claims 73-104 are patentable over the cited references.